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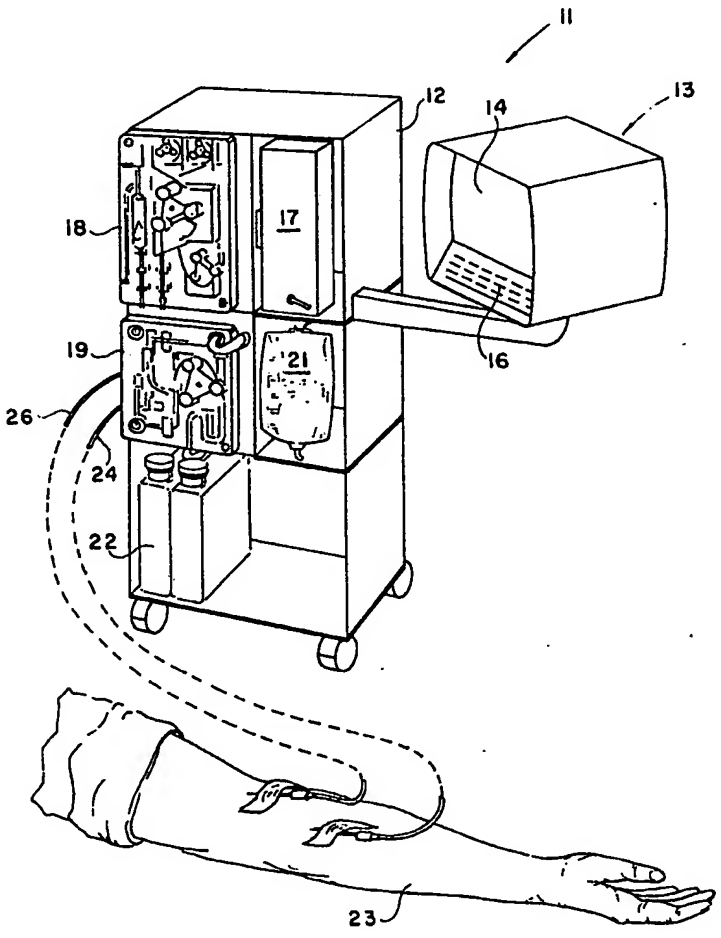
(71) Applicant
Elmar Medical Systems Limited
(Israel),
P.O. Box 5390, Haifa, Israel
(72) Inventor
Avinoam Livni
(74) Agent and/or Address for Service
Marks and Clerk,
57—60 Lincoln's Inn Fields, London WC2A 3LS

(54) **Blood treatment system**

(57) An extra-corporeal blood treatment system, particularly a haemodialysis system, is provided, the system comprising a machine (12) having a blood treatment device, tube means (24, 26) removable from said machine for connecting a patient's cardiovascular system to the treatment device, characterised in that said tube means (24, 26) comprise tube sections within cassette means (18, 19) and means are provided for coupling the cassette means (18, 19) to the machine (12) and thereby automatically connecting the tube means (24, 26) to the proper places for connection to and operation of the blood treatment device.

Fig.1



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The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

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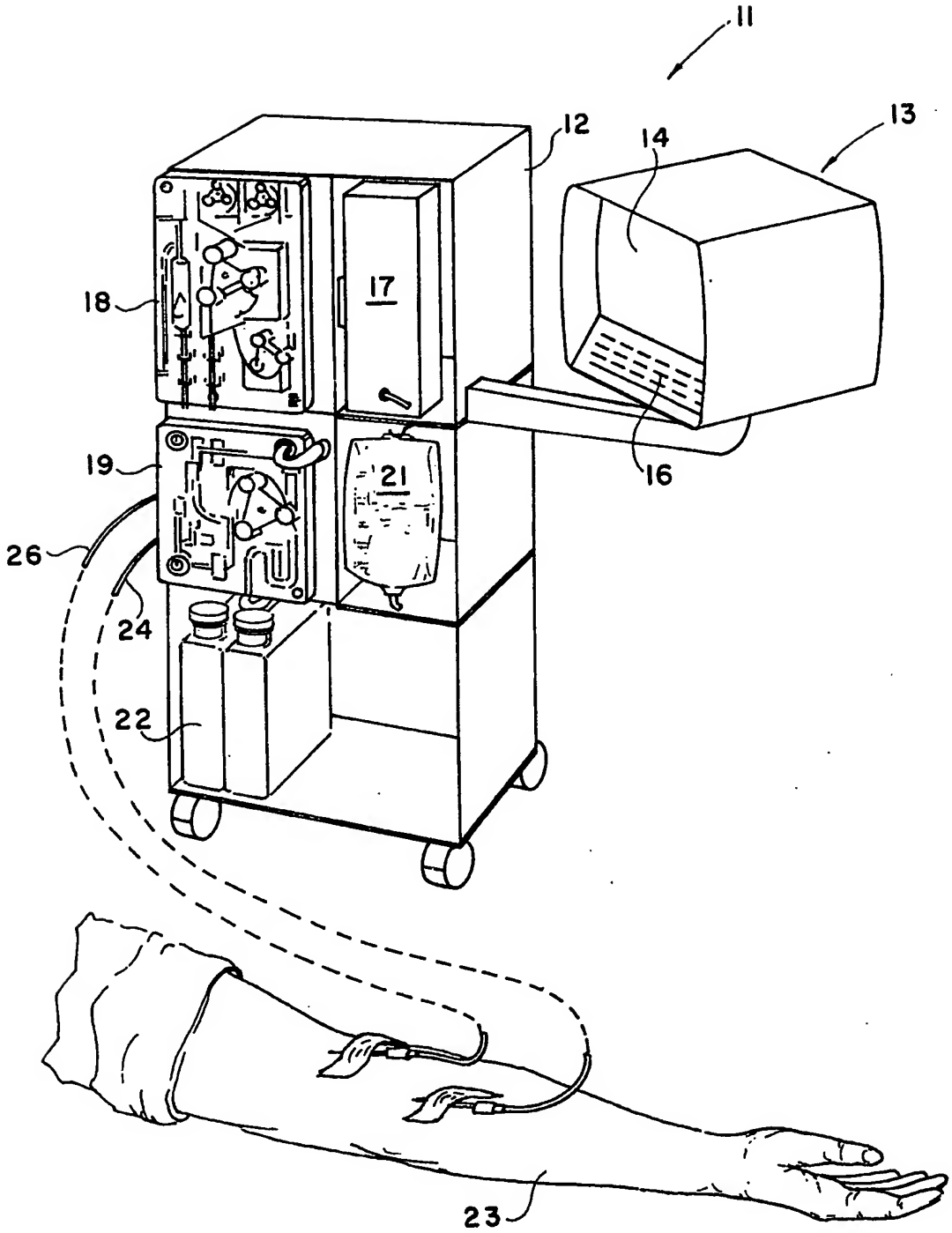
Fig. 1



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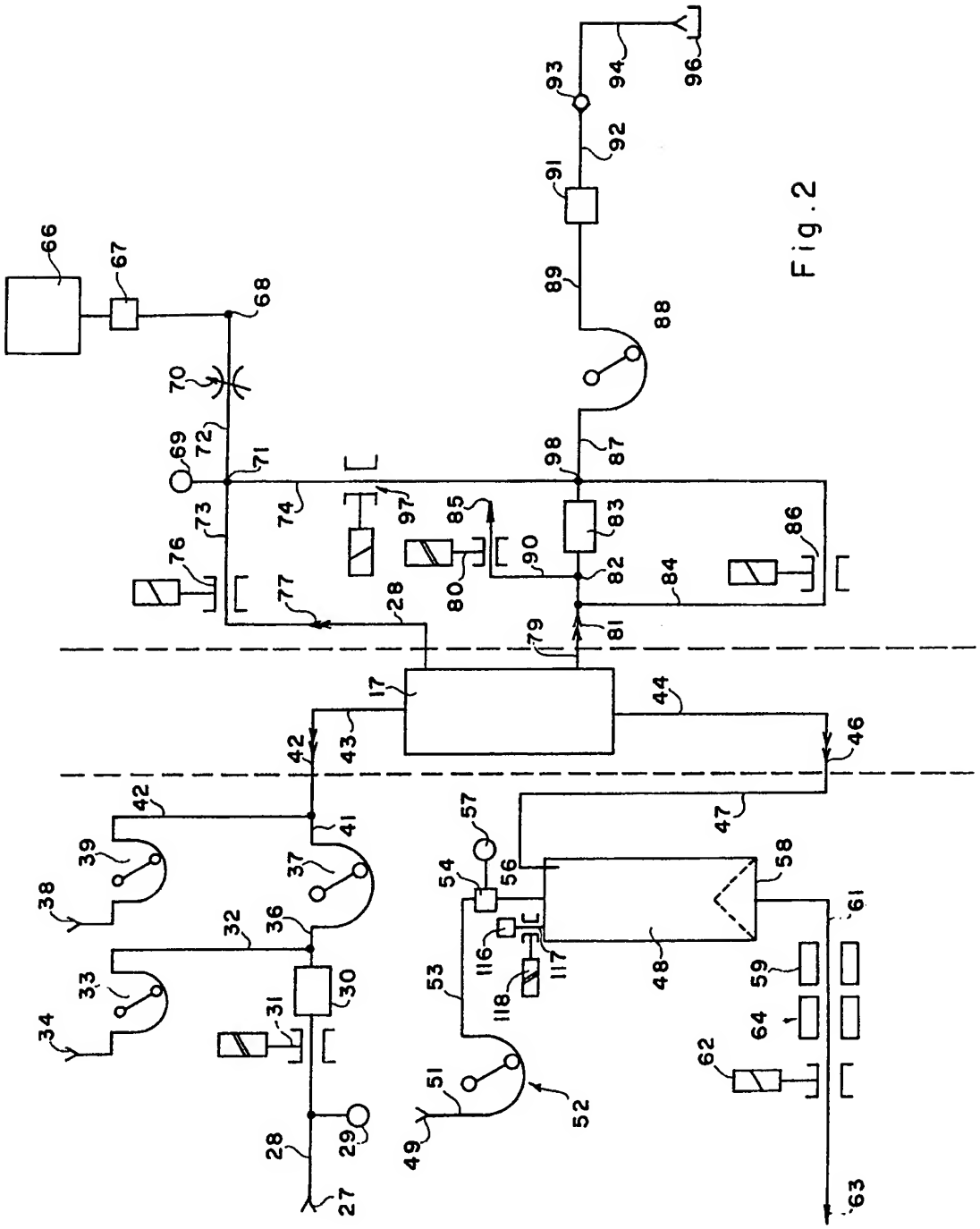
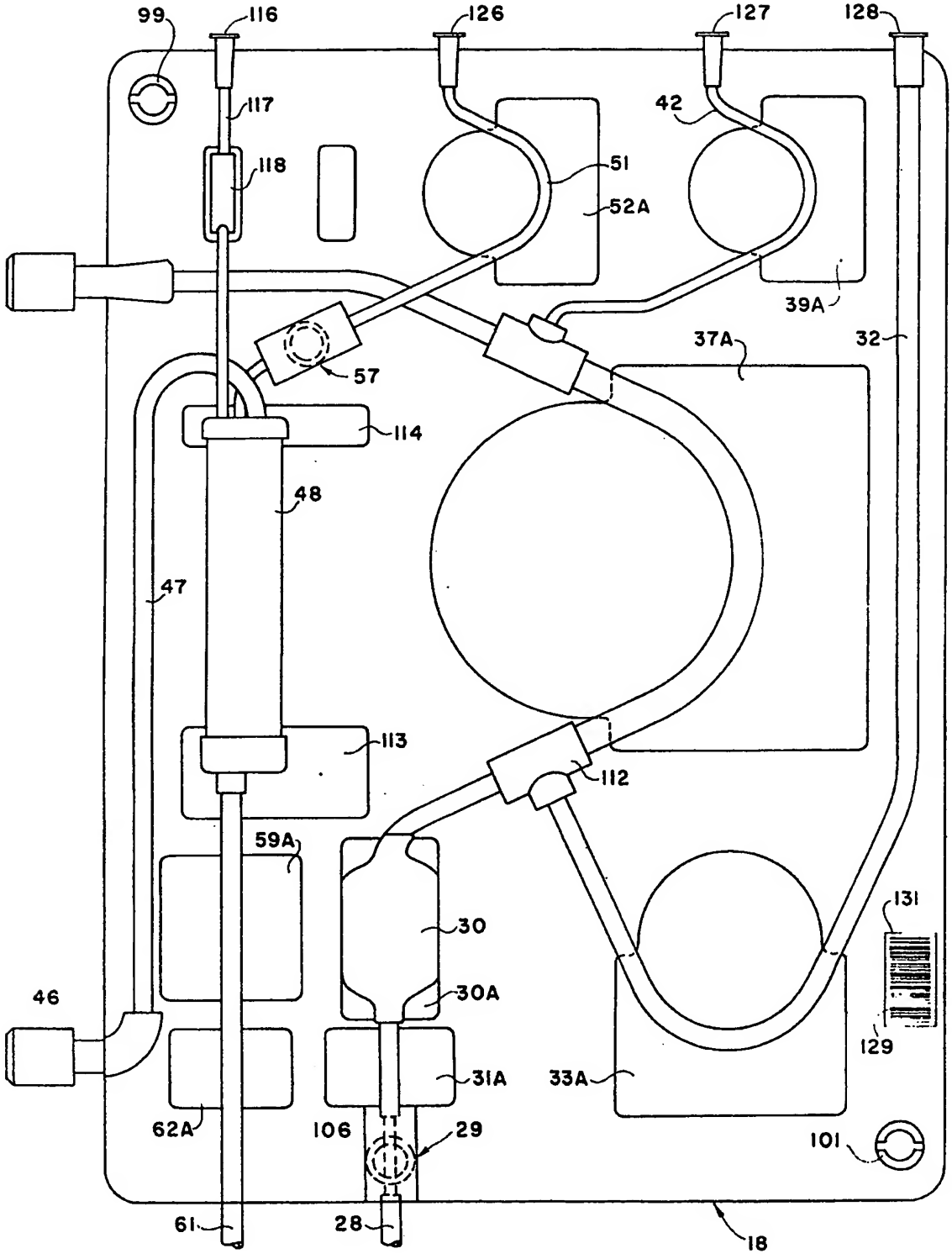


Fig.2

Fig.3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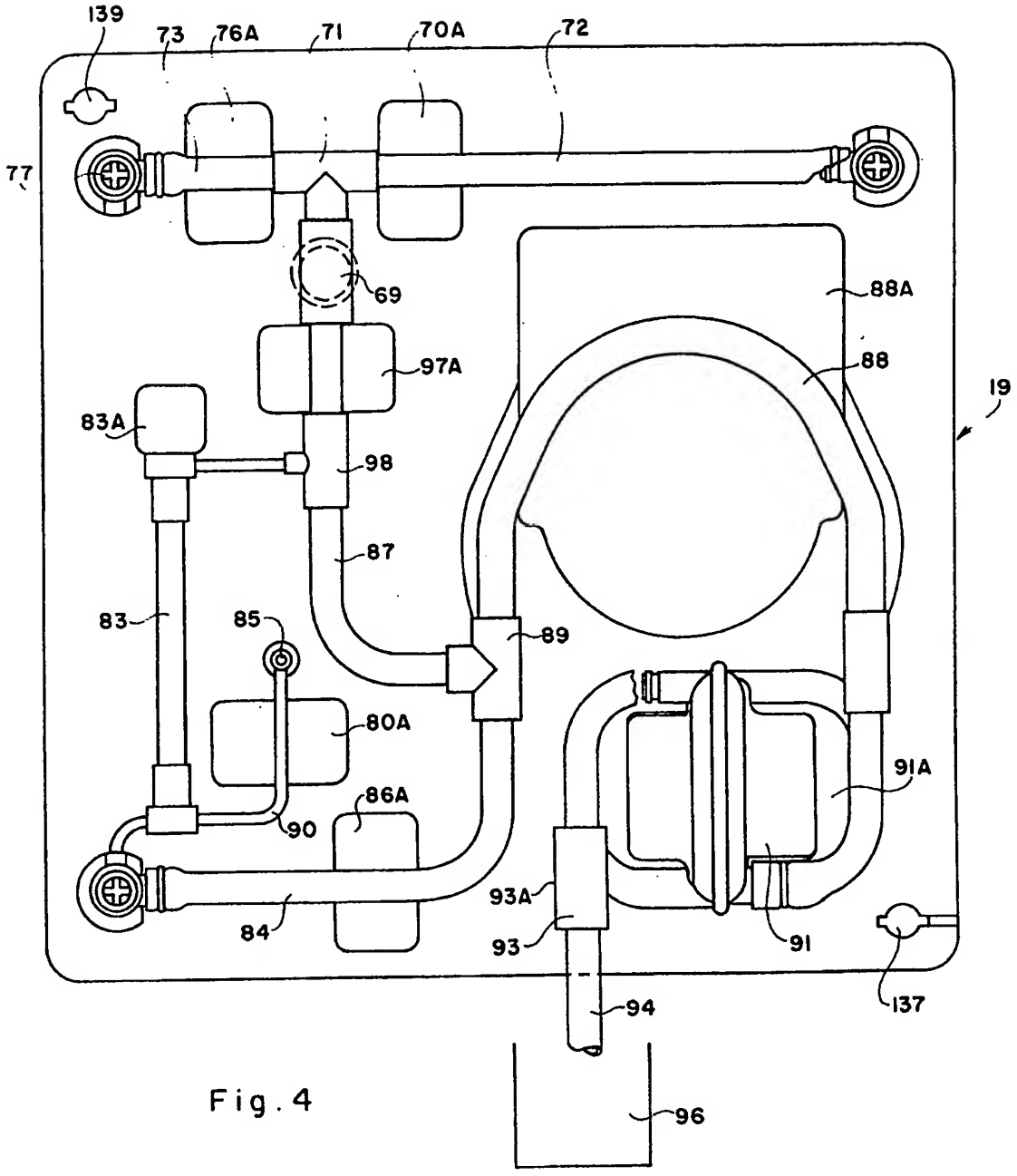


Fig. 4

Fig. 6

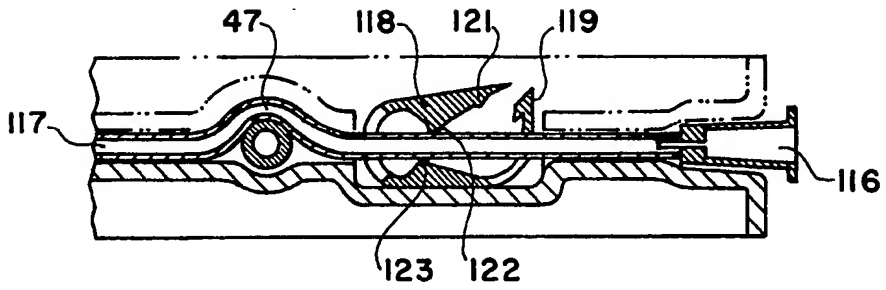
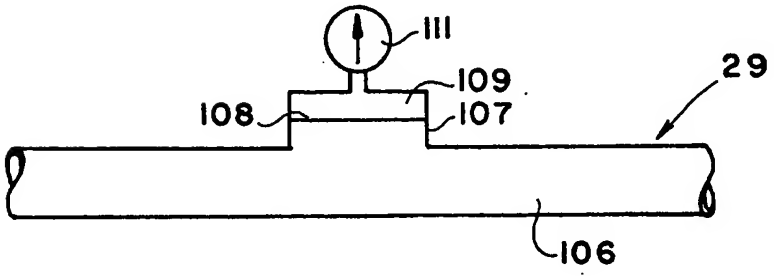


Fig. 5



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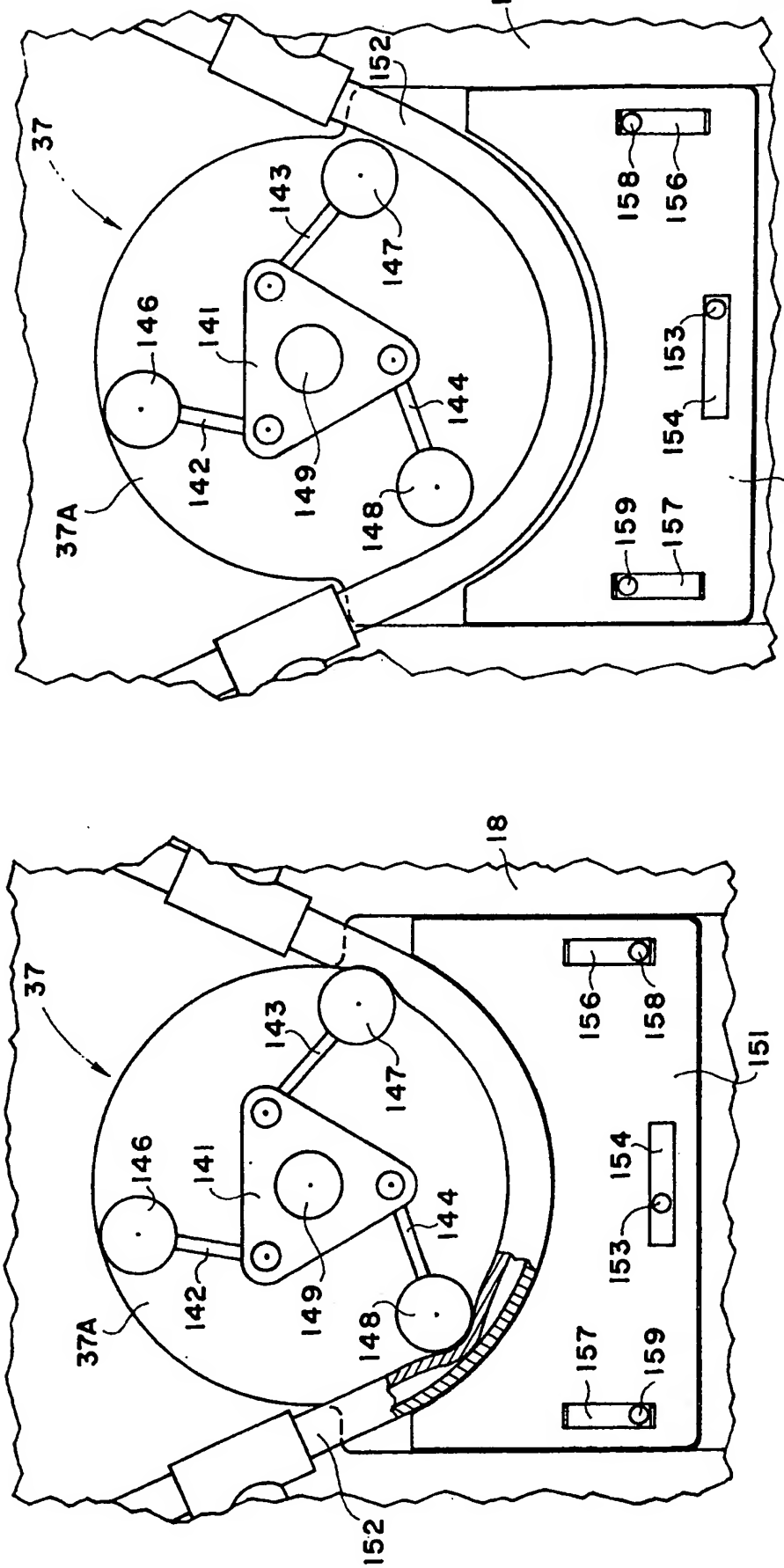

Fig.7

SPECIFICATION

Blood treatment system

This invention is concerned with the treatment of blood for use in curing or aiding patients with problems of the blood and more particularly with systems which perform such treatment extra-corporeally.

The treatment of blood done external to the body is well known. A prime example of systems for such treatment are the artificial kidney machines wherein the blood of a patient is directed through the system and performs the filtering and cleansing operation no longer performed adequately by the kidney. The present-day machines in use have serious shortcomings. For example, the appearance of the machines is frightening. There are tubes exterior to the machine running every which way, some carrying blood and some carrying saline solutions.

In addition to being frightening to look at, the present day machines are also potentially dangerous in use. Such diseases as hepatitis could easily be spread through the use of such machines. Therefore prior to connecting patients to such machines, it is necessary to completely cleanse and sterilize the machines to prevent the spread of dangerous germs. To this end the tubes which carry the blood and saline solution are all removed and cleansed or thrown away and clean tubes or new tubes are reconnected to the machine. The cleansing operation takes a great deal of time and effort and must be performed by reliable personnel.

A further drawback of the present day machine is that often prior to cleansing the machines must be reconnected with the cleansed or new tubing. The reconnection process is an area where serious errors can occur. Thus, for example if a tube is incorrectly connected from one point to another there could be extensive damage or at the very least a frightening experience for the patient since the machine will turn on, the blood will start flowing and the machine will automatically turn off and set up alarms which are normally both visual and aural.

In addition to the tubing, parts of the machine are continuously reused, such as, for example the pump equipment for moving the blood and the saline solutions and certain sensing devices such as for example, flow meter arrangements and liquid level sensing devices. It is preferable of course that such devices be new for each patient. Of course that makes the treatment inordinately expensive. Therefore it is necessary to adequately clean such devices prior to re-use. The necessity for hand cleaning such equipment adds to the time dispensed in the preparation of using the machines and therefore adds to the burden of using such machines.

Accordingly there is a long-felt need for an extra-corporeal blood treatment system wherein all the blood or solution contacting portions are either dedicated to a single patient and/or of the throw-away variety without unduly complicating the system and without inordinately increasing the expense of the system. There is also a long-felt need to provide such systems wherein the connections between the system and the patient and between different parts of the system made by tubing in a manner that prevents an awesome and frightening picture to the users and potential users of the machine. Also, there is a long-felt need to provide such systems wherein the connections for the flow of blood, saline solution or dialysate can be made with the minimal possibility of error.

Accordingly it is an object of the present invention to provide new and improved extra-corporeal blood treatment systems in which the above-referred to disadvantages are substantially reduced or overcome and the above-referred to requirements are substantially provided.

According to the present invention an extra-corporeal blood treatment system is provided, said system comprising a machine having a blood treatment device, tube means removable from said machine for connecting the blood circulation system of patients to the treatment device, and said tube means comprising tube sections within cassette means, means for coupling the cassette to the machine and thereby automatically connecting the tubing to the proper places for connection to and operation of the blood treatment device.

A further feature of the invention is the capability of dedicating the cassettes to particular patients such as, for example, by using magnetic, electrical, optical or mechanical coding of the cassettes.

Another feature of the invention is individualized cassettes for handling solutions such as dialysate often used in blood treatment whereby there is a minimum of tubing external to the cassettes provided, which external tubing can economically be discarded and replaced by new tubing for each patient or for each use of the machine and system.

In accordance with a further feature of the invention the cassettes are fashioned so as to enable easy and simple removal of the tubing sections within the cassette after each use, the used tubing sections being discarded and the rigid cassette shell, optionally after cleansing, being reloaded with a fresh set of tubing. This procedure is applicable both to cassettes of the throw-away type and to individualized cassettes dedicated to particular patients and has the advantage of saving the cost of the cassette shell.

Yet another feature of the invention is cassette means which cooperate with pumping means whereby the pumping is accomplished on the tubing in the cassette so that the individual pump parts do not require sterilization prior to use with each patient.

Still another feature of the invention is unique flow meter devices wherein the actual measuring is done external to the tubing of the cassettes so that the sterilization process and the chances of errors are minimized.

Yet another feature of the invention is unique

metering devices wherein the body liquids or treatment solutions are confined within the cassette component thus maintaining complete sterilization and minimizing errors.

The operation and utilization of the present invention will be more fully apparent from a description of a preferred embodiment taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a pictorial showing of the system used as an artificial kidney wherein both blood tubing cassette and dialysate cassettes are shown as provided;

Fig. 2 is a flow diagram for such a system when used in haemodialysis;

Fig. 3 is a plan view of a typical blood cassette;

Fig. 4 is a plan view of a typical dialysate cassette;

Fig. 5 is a partially sectional view of a pressure meter in the tubing in a blood cassette;

Fig. 6 is a sectional view taken at 6—6 showing a hand operated clamping device in the open position; and

Figs. 7A and B are showings of the cassette pump slots with the pump therein in the loading and operational positions, respectively.

In Fig. 1 the extra-corporeal blood treatment system 11 is shown as comprising a basic machine 12 having automatic control apparatus including input and readout apparatus 13 shown as comprising a CRT 14 and the keyboard 16 for the input of instructions. The basic machine is shown as including a dialysis filter or dialyser 17.

The flow diagram of Fig. 2 schematically shows what is contained in the blood cassette 18 and in the dialysate cassette 19. In between the cassettes as defined by the dashed lines is the filter 17. Certain other parts of the machine are not shown, such as, for example a bubble trap, a heater and other such parts which are well known to those skilled in the art. The flow diagram starts from coupler means 27 past the arterial blood pressure transducer chamber 29 within the cassette and provides on an external meter a reading on the arterial blood pressure. Thus the transducer chamber of the external meter is integral to the cassette.

A clamp 31 is also provided near the beginning of tube 28. Clamp 31 can be any type of clamp; however in a preferred embodiment it is automatically operated by the machine logic. The clamp operates in certain emergency conditions to close the tube. Thus when the cassette is attached to the machine the clamp 31 is open but enabled. When an emergency condition arises that requires the machine to stop functioning the clamp is closed.

Means are provided for adding saline solution to the blood. More particularly a tube 32 connects from a pump 33 which is in series with an inlet coupling 34 to which a container of saline solution is attached. The junction of tube 28 and 32 is coupled at 36 to a main blood pump 37. The blood pump 37 is briefly described herein and is described in detail in the co-pending application filed simultaneously herewith and entitled "Peristaltic Pump".

At the output of the blood pump an anti-coagulant such as heparin is mixed with the blood and the anti-coagulant port is indicated at 38. A pump 39 for the anti-coagulant is coupled by tube 42 through "T" coupling 41 to the blood pump 37.

The filter 17 is connected to "T" coupling 41 by tubing 43. The filter is any of the commercially available closed negative pressure type filters.

The outlet of the filter 17 is connected back to the cassette 18 through tube 44 and inlet coupling 46 of the cassette 18. The inlet 46 is attached to the tubing 47 in the cassette. The tubing leads to a drip chamber 48. The drip chamber 48 is attached to tube means 53 used for removing air from the drip chamber through pump 52, tube 51 and port 49 to maintain the desired liquid level in the chamber. The pressure in chamber 48 is shown by gauge 57.

A blood level detector 58 is associated with the drip chamber. Any type of blood level detector can be used. In a preferred embodiment however an inventive blood level detector is used and is described in the co-pending application entitled "Liquid Sensor Systems" filed simultaneously herewith.

A flow meter 59 coupled by tubing 61 to detector 58 is provided at the outlet of the drip chamber. In a preferred embodiment a unique flow meter operates without any internal instrumentation in contact with the blood. This of course aids in maintaining the sterility of the system. The unique flow meter is described in the co-pending patent application mentioned immediately hereinabove.

A bubble detector means 64 is provided for detecting any bubbles that happen to get by the drip chamber. Also provided immediately at the end of tube 61 is an automatic clamp means shown as vein clamp 62. The tubing 61 leads to the outlet coupling 63 which connects to tubing 26 leading to a needle in a vein of the patient or any other means of attaching to the venal system of the patient.

The flow diagram of Fig. 2 also describes that portion of the flow system which is in the dialysate cartridge 19. A dialysate source 66 is connected through various devices such as heaters and measuring devices indicated generally at 67 to the cartridge at coupler 68. Immediately thereafter there is a variable restrictor 70 for controlling the negative pressure of the dialysate solution. After the restrictor 70, means are provided for measuring the pressures such as for example dialysate pressure transducer and gauge arrangement 69. The transducer and gauge arrangement 69 is coupled to a "T" coupler 71 extending from tube 72 to tubes 73 and 74. Tube 73 leads to an automatically operated dialysate inlet clamp 76. The tubing 73 downstream of the clamp 76 is connected to the filter 17 through couple 77 and filter tubing 78.

The outlet of the filter 17 goes through filter

tubing 79 and coupling 81. From coupling 81 tubing 82 in the cassette leads through a flow monitoring arrangement 83. The flow monitoring arrangement can be any well known type of monitoring arrangement. However in a preferred embodiment an ultrasonic flow meter was used and is described in detail in the above-referred to patent application. Bypassing the filter is tubing 74 which is provided with a means for closing off the by-pass such as the by-pass clamp 97. The tubing 74 couples to tubing 87 and 84 at coupling 98. The outlet of the flow monitoring arrangement 83 goes through tubing 87 to a dialysate suction pump 88. From the pump 88, the fluid is forced through tubing 89 and a blood leak detector for assuring that the membrane in filter 17 has not ruptured. The outlet of detector 91 is directed through tubing 92 and check valve 93 through tubing 94 to drain shown as 96.

Every three minutes, for example, the machine transfers to the by-pass mode by opening by-pass clamp 97 and closing inlet and outlet clamps 76 and 86, respectively, in order to measure the ultrafiltration rate. Thus the ultrafiltration rate measurement is accomplished by sampling. Note that the negative pressure on the filter is maintained through the flow monitoring arrangement 83. The sampling measurement is the input for the computer that computes the negative pressure and controls the restricter to provide the negative pressure required for maintaining the desired ultrafiltration rate.

The cassettes 18 and 19 contain most of the tubing of the system that can be dedicated to a single patient. The remainder of the tubing and devices are associated with such things as the filter heating arrangement and concentrate mixing devices which can be cleaned in a minimal time and sterilized in the machine by following certain sterilization procedures without the necessity of replacing and/or sterilizing a lot of tubing and then properly coupling the tubing with the machine. All of the tubing not within the cassette do not come in contact with the patient's blood extracts and therefore are subject to less critical sterilization requirements.

In Fig. 3 the blood cassette is shown generally at 18. In a preferred embodiment cassette 18 is a plastic unit similar in many respects to the cassettes used in tape players. There are in this preferred embodiment two mounting holes 99 and 101 placed at diagonally opposite corners of the cassette. There are of course posts (not shown) on the machine on which the cassettes are mounted by positioning the cassette so that the posts fit through the holes 99 and 101. The cassette is then pressed down until it is juxtaposed to the machine. The cassette actuates certain switches (not shown) when in position. The operation of the switches enables the pumps, automatic clamp and certain sensors so that they operate responsive to the operation of an "ON-OFF" switch (not shown) to the "ON" position. The cassette is then locked in place. As is readily seen the cassette contains actual tubes. A feature of the cassette are the apertures and slots enabling the cassette to operate with other equipment such as clamps, pumps and sensors in the machine. There are slots, for example, such as slots 31a where the patient's blood is first brought into the system. Slot 31a is made to accommodate a clamp on the machine having a solenoid or a pneumatic actuator for use in automatic mechanised operation of the clamping surfaces. Similarly the apertures 33a, 37a, 39a and 52a are designed to receive tubing therein in a manner so that the tubing meshes with the rotary pump rollers and stators attached to the machine. The unique rotary pumps used have movable stators which are automatically actuated responsive to operation of the previously mentioned switches. Pumps of this kind serve both to force flow of the fluid and as valves for enabling and inhibiting the flow of fluid.

There are pumps shown for the saline solution, for the anti-coagulant solution and the like. It should be noted at this point that such solutions can also be added using gravitational feed with controlled valves. However in a preferred embodiment the solution volumes are controlled using pumps.

The pressure transducers and gauges are shown in more detail in Fig. 5. Pressure transducers such as pressure transducer chamber 29 associated with tubing 28 is constructed to minimize contamination of the fluids flowing in the tubing of the cassette.

The cassette 18 is shown as being equipped with two pressure measuring transducer chamber arrangement 29 and 57. They both operate in the manner shown in Fig. 5. There the pressure transducer arrangement 29 is shown as comprising some soft narrow tubing shown as tubing 106 for example. There is a cylindrical section to the tubing 107 separated from the tubing by a diaphragm 108. Above the diaphragm a fluid is stored shown as 109. As the pressure in tubing 106 varies the pressure on the fluid 109 varies, changing the reading on the gauge 111.

An opening 103 in the cassette is also provided to accommodate accumulator 30. The accumulator is made of a resilient material to provide volume to the fluid going into the pump 37 through the "T" fitting 36. The accumulator acts to assure that the flow from the pump is steady. It filters out surges caused by the rollers of the pump. The accumulator also acts as a volume storage for the single needle mode of operation.

Openings 113, 114 are also provided in the cassette and relate to the drip chamber 48. These openings accommodate the instrumentation for detecting the liquid level in the drip chamber. Similarly there is an opening 59a shown below the drip chamber to accommodate the unique blood flow meter and air bubble detector.

The cross-section of Fig. 6 gives an idea of the thickness of the cassette as well as showing how the tubing fits into the plastic cassette. The tubing shown in Fig. 6 is the tubing leading from a port 116 used for adding medications and the like to the blood being processed. The port 116 leads to

tubing 117 that is shown clamped with clamp 118. The tubing 117 goes directly to the drip chamber 48. The clamp 118 is shown as a manually operated clip type clamp having a clip section 119 for receiving and retaining the resilient lever section 121 at which time the clamping points 122 and 123 provide sufficient pressure on tubing 117 to close the tubing. The ports such as ports 116, 126, 127 and 128 are designed to accommodate bacteria filters in series with the tubing.

The cartridge also has a coding identification means shown generally as identification means 129. The identification shown are the well known series of magnetized surfaces. The patient is provided with a card also having such holes. The card is placed into a slot on the machine. If the codes match, the system is enabled. The dedication coding can take any of various forms well known to those skilled in the art and is not limited to the magnetic technique, of course.

The dialysate cassette 19 is shown more particularly in Fig. 4. Here again, mounting holes such as holes 136, 137 are shown disposed at opposite diagonal corners. The cassette 19 also features slots and apertures therein. There is an aperture 88a for the dialysate pump. There are also clamping apertures disposed adjacent the inlet and at the outlet tubing. The inlet clamping aperture is denoted as aperture 76a for accommodating clamp 76. The variable restrictor 70 of the flow diagram is accommodated in aperture 70a. An aperture 97a is provided for the by-pass clamp 97. The aperture 86a is for accommodating the outlet clamp 86. An aperture 91a is also provided for the blood leak detector 91. The check valve 93 is coupled right into the line and there is a widened slot 93a in the cassette to accommodate check valve 93.

The cassette 19 contains means for measuring the water extraction rate of the filter. In the prior art there are many ways of measuring the water extraction rate. Any of those prior art ways could conceivably be used within this cassette system. However in a preferred embodiment use is made of a unique water extraction rate measuring device that includes an ultrasonic transducer. The rate monitor is indicated in the flow diagram Fig. 3 and there is provided in conjunction with the monitor device a cavity 83a for accommodating an ultrasonic transducer that is in the machine. A sample port 85 may be provided. Thus there is shown a manually operated clamp 80 operating on a tube 90 extending from "T" fitting 82 to port 85. An aperture 80a in the cassette receives the clamp 80. An aperture 91a accommodates the blood leak detector unit 91.

The tubing numbers in Figs. 3 and 4 are the same as tubing numbers of the flow diagram and therefore are not repeated in the interests of clarity and brevity.

The dialysate pressure transducer 69 operates in a manner already described.

Thus as with the blood cassette the dialysate cassette is relatively small and compact, easy to clean, contains means such as dedication coding means 139 for dedicating the cassette to an individual patient. The fittings 68, 77 and 81 facilitate the use of the cassette by automatically coupling its tubing to the machine.

The pump 37 is shown in Figs. 7A and 7B of the cassette 18, to aid in understanding the usefulness of the cassette. The pump comprises a rotor 141. Mounted to the rotor by links 142, 143 and 144 are a plurality of rollers 146, 147 and 148, respectively. The rollers describe a cylindrical locus as the rotor rotates about rotor axis 149.

The stator 151 is movable between a loading position (Fig. 7A) and an operate position (Fig. 7B). In the loading position the stator is removed from the locus described by the rollers so that when the cassette is mounted on the machine the tubing 152 easily and automatically fits between the rotor and the stator.

In the operate position the locus described by the rollers abuts the tubing 152 to provide the pumping action desired. The stator is moved by rotation of a cam member 153 in slot 154. Means such as slots 156 and 157 with pins 158 and 159 extending therethrough from the machine maintains the linearity of the stator movement. Thus when the cassette is placed on the machine the tubing of the cassette fits between the stator and the rotor. Pushing the cassette into position actuates a solenoid (not shown) which turns the cam member 153 to move the stator to the operate position.

In operation the patient is prepared and the machine is brought to the patient, the cassettes are placed in the machine. The coding is checked to ascertain that it is the cassette dedicated to the individual patient. The needles are placed into the patient's arm and the machine is operated by operating a start switch. The clamps and pumps operate for taking the blood from the patient and placing it into the filter to extract the poisons therefrom in a manner known for automatic kidney machines. In addition to enabling the automatic operation of the clamps, the placing of the cassettes on the machine automatically positions and controls the pumps for proper operation. The pumps are operated responsive to the program that is inserted into the memories of the machine using the keyboard by the CRT shown in Fig. 1.

One of the advantages of the cassettes is to make it safer to utilize dialysis equipment at home. With the cassettes there is no need for concern about proper connections for the tubing. It should be noted, in this respect, that while a relatively large machine in drawing, more compact machines using the equipment described herein can be used at the patients' homes.

Another advantage of the cassettes is that they can easily be washed and sterilized while still on the machines. After the machine is disconnected from the patient it is connected to be rinsed using the pumps on the machine to force the rinsing fluid through the cassettes. Subsequently a sterilizing solution is pumped through the

cassettes. The cassettes may be stored between uses with the sterilizing fluid therein.

While the principles of the invention have been described above in connection with specific apparatus and application, it is to be understood that this description is made by way of example only and not as a limitation on the scope of the invention.

CLAIMS

1. An extra-corporeal blood treatment system comprising:

a machine having a blood treatment device,

tube means removable from said machine for connecting patient's cardio-vascular system to the treatment device, and

said tube means comprising tube sections within cassette means.

2. The system of Claim 1 including individualized coding means, wherein said tube means comprises individualized cassettes, said cassettes containing crucial portions of the tubing therein.

3. The blood treatment system of Claim 1, wherein the treatment device is a haemodialysis treatment filtration means.

4. The system of Claim 3, wherein a dialysate system cassette is provided in addition to blood system cassette.

5. The system of the previous claims wherein pump means operate on the tubes in the cassettes to force the flow of blood and dialysate.

6. The system of Claim 5 including flow meters operating in conjunction with said cassettes.

7. The system of Claim 6 wherein liquid level measuring system is provided for operating in conjunction with the cassette to measure the liquid level in a drip device.

8. The system of Claim 1 wherein said cassette means comprises slots for receiving devices on the machine therein to enable operation of the devices with said tubing in said cassette.

9. The system of Claim 8 wherein said devices include pump means for causing movement of fluid through said tubing.

10. The system of Claim 9 wherein said fluid includes saline solution.

11. The system of Claim 9 wherein said pump means comprises rotor means and stator means, said stator means having a loading position removed from said rotor whereby said tubing can be automatically positioned between said rotor and said stator and an operating position wherein said rotor compresses said tubing against said stator to provide pumping action when said rotor rotates.

12. The system of Claim 9 wherein measuring means are provided for determining the amount of water removed from the patient.

13. The system of Claim 12, wherein said measuring means comprises means for bypassing the flow of dialysate around said filtration means, means for maintaining a negative pressure at the dialysate portion of said filtration means, and dialysate pump means coupled through flow monitoring means between said dialysate portion of said filtration means and drain.

14. The system of Claim 9 and means for successively coupling rinsing fluid and sterilization fluid to said machine for being forced through said cassettes by said pumping means.

15. An extra-corporeal blood treatment system substantially as hereinbefore described with reference to the accompanying drawings.

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